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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,135	02/05/2002	David Wayne Schroeder	5490-000220	7517
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HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				
			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3732	PAPER NUMBER 8
DATE MAILED: 11/21/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,135

Applicant(s)

SCHROEDER, DAVID WAYNE

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/7/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-14, 17-22, 24, 25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-14, 17-22 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 3, 8, 24, 25 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2002 and 09 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Objections

Claims 3, 8, 21, 24, 25 and 30 are objected to because of the following informalities.

Claim 3 is objected to because of "the texture." It is suggested that this word be replaced with a suitable term to be consistent with claim 1.

In claim 8 it is suggested that "shape" (line 3 and line 4) be replaced with "surface" for clarity.

In claim 21, the Applicant is requested to check the use of the word "texture" and ensure that it is consistent with the claim language.

Claims 24 and 25 depend on cancelled claim 23 and are therefore considered cancelled.

Claim 30 appears to depend from claim 19. Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the following claimed subject matter:

In claim 1, line 9: "plurality of radially disposed macro-grooves."

In claim 8, lines 3-4: "macro-grooves areshape."

In claim 18, lines 3-4: "macro-grooves areinsert."

In claim 19, line 11: "plurality ofmacro-grooves."

In claim 20, line 10: "plurality ofmacro-grooves."

In claim 21, lines 6-7: "plurality ofmacro-grooves."

Appropriate correction is required. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-5, 8-14, 17-19, 21-22 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. (US 5,879,404) in view of Asthana et al. (US 2003/0175488), further in view Shelley (JP402161943).

Bateman et al. disclose a composite acetabular component having a ceramic bearing liner or "insert member" 2 and an outer shell or "backing member" 3 wherein the outer shell is made of a thermoplastic material such as polymethylmethacrylate, polyethylene or ultra-high molecular weight polyethylene (col. 1, lines 30-39, col. 2, lines 43-47, lines 66-67 and col. 3, lines 1-4).

Bateman et al. further disclose a method of making a composite acetabular component having the steps of: providing a ceramic insert member 2; providing a thermoplastic material; softening the thermoplastic material (e.g. injection or compression molding (col. 4, lines 37-41); and contacting the outer surface of the ceramic insert member 2 with the softened thermoplastic material to form backing member 3 around insert 2 (col. 4, lines 27-33 and lines 37-41).

Bateman et al. do not disclose that the outer surface of ceramic insert 2 is provided with texture and radially disposed macro-grooves.

Asthana et al. teach that adhesion between a polymer layer and an underlying substrate or ceramic layer is enhanced by providing a texture to the surface of the ceramic layer (para [0006], lines 11-14, para [0028] and para [0129]-[0132]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the composite acetabular component of Bateman et al. with the outer surface of insert member 2 having a texture, in view of Asthana et al., in order to enhance adhesion of insert 2 with backing member 3.

Shelley teaches a composite acetabular component having a metallic outer shell or cup and a plastic insert 9 wherein radial grooves 16 are provided on the inner surface of the cup to prevent rotation of insert 9 within the cup. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided radial grooves 16 on the ceramic bearing insert 2 of the acetabular component of the combination of Bateman et al. and Asthana et al., to prevent rotation of bearing insert within the outer shell, since it has been held

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that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

With regard to claims 4-5 and 13-14 it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the composite acetabular component of the combination of Bateman et al. and Asthana et al., as modified by Shelley with a texture or "roughened surface" having an arithmetic mean roughness in a range of about 5 to about 10 microns or a ten-point mean roughness in a range of about 50 to about 75 microns since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 8, the Applicant has failed to establish the criticality of the macro-grooves having a longitudinal orientation with respect to the hemispherical surface of the insert. It is the Examiner's opinion that any orientation could be used and thus the device of the combination of Bateman et al., Asthana et al. and Shelley would perform equally well as the claimed invention.

With regard to claim 19, Bateman discloses an acetabulum replacement system including an acetabulum member 12 and a composite acetabular component having a ceramic insert member 11 and a thermoplastic backing member 13 wherein the composite acetabular component is secured or molded to the acetabulum member 12 (Figure 5 and col. 5, lines 41-48). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the acetabulum replacement system of Bateman et al. with the outer surface of insert member 11 having a texture, in view of Asthana et al., to enhance adhesion of insert 11 with backing member 13, and radially positioned macro-grooves, in view of Shelley, in order to prevent rotation of insert 11 in backing member 13.

With regard to the method steps of claims 21-22 and 28-30, the step of imparting a texture to the outer surface of ceramic insert member 2 and contacting the textured outer surface of ceramic insert member 2 with the softened thermoplastic material, it is noted that these steps are inherent in the combination of Bateman et al., Asthana et al. and Shelley.

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. in view of Asthana et al. and Shelley, further in view of Sherman (US 4,936,855).

Sherman teaches a conventional hip replacement system as having an acetabulum-type cup member and a spherical head member which mates with and is rotatably supported by the spherical cavity of the cup member for articulated motion associated with the hip joint (col. 1, lines 46-58).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a hip replacement system as taught by Sherman wherein the acetabulum-type cup member is the acetabulum replacement system of the combination of Bateman et al., Asthana et al. and Shelley (see previous discussion for claim 1) wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in a conventional hip replacement system.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 8-14, 17-19, 21-22 and 28-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's attention is specifically directed to the following patents.

US 5,480,448 (Mikhail): Figure 5 and col. 4, lines 53-62.

US 6,132,469 (Schroeder): col. 3, lines 15-24.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anunadha Kanara*
November 15, 2003

Kevin Shaver
KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700